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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,069	10/24/2003	Frank Himmelsbach	5/1315-1-C1	3373

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MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,069	HIMMELSBACH ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *10/081,826* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/11/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Although this case is labeled as a CON of the parent, the examiner notes for the record that the original claims in this case were not the original claims in the parent, but correspond to the amended claims of the parent.

The rejections over Kanstrup and Chackalamannil were overcome by those amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chackalamannil.

See above rejection. Although the compounds are not in the salt form, the reference teaches salts generally, see paragraph 0081. Hence, their use would be obvious.

Claims 1-2 and 8-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 37-4895.

See the attached index sheet which shows the relevant species, and the translation. This corresponds to the R4 = NR15R16 choice, where R16 is diethylamino propyl. The sole difference is that the claim requires R15 as methyl, while the reference has H. Such a variation is considered obvious because of the close structural similarity. See *In re*

Hoeksema, 154 USPQ 169; *Ex parte Weston*, 121 USPQ 428; *Ex parte Bluestone*, 135 USPQ 199; *In re Doebel*, 174 USPQ 158. Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness"; one of those listed is "adjacent homologues and structural isomers". Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." The salts and use as diuretics is disclosed.

With regard to claim 11, the reference shows method a), with the process corresponding to Z1 = Br.

Claims 1, 2, 8-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leake.

See examples 23-28 and 30-32, some of which have salts as well. With regard to claim 2, which has the dimethylaminoethyl (see 10th from last line of page 25), these mostly have diethyl rather than dimethyl, but the generic teaching is dialkyl, and example 24 has the dimethyl, such a variation would be obvious. These compounds lack the extra methyl

group, and would hence be obvious for the reasons given in the above rejection. With regard to claim 11, the reference shows method a), with the process corresponding to Z1 = Cl.

The traverse is unpersuasive. The situation with regard to the declarations is unclear. Applicants submitted a Declaration in the parent ("Himmelsbach I"). Applicants have not tendered a copy of this declaration in this case, and the remarks make no mention of this declaration. On the other hand, this new declaration ("Himmelsbach II") does make a reference to the early declaration. Thus, it is not clear whether applicants intend or do not intend to rely on the earlier declaration. To advance the prosecution of this case, the Himmelsbach I declaration will be discussed, but if applicants wish to rely on this, which seems unlikely, they must submit a copy for this applicant as well.

With regard to Himmelsbach I:

1. The declaration presents conclusions without supporting facts, and as such it is entitled to little or no weight, cf. *In re Etter*, 225 USPQ 1, 6; *In re Grunwell*, 203 USPQ 1055, 1059; *In re Buchner*, USPQ2d 1331; *In re Chilowski*, 134 USPQ 515,521; *In re Brandstadter*, 179 USPQ 286, 293-294, *In re Thompson*, 192 USPQ 275; *Ex parte George* 21 USPQ2nd 1058, 1062. No evidence was presented that the desired compound was not present along with the tricyclic compound, nor was evidence presented that the prior art procedure was followed.

2. The fact that declarant failed to make the prior art compound is not necessarily dispositive of the issue; it does not necessarily render the reference non-enabled. As was stated in *In re Lamberti*, 192 USPQ 278 (CCPA 1976), "At best, appellants have merely shown that it is possible to follow the process in one example each of MacGregor and Cisney without success. And even then, there is no showing that one of ordinary skill in the art, making adaptations within the skill of the art, could not have successfully carried out each

process." Applicants have not tried any such adaptations. The same thought appears in *In re Michalek*, 74 USPQ 107, which states, "With respect to the experiments described in the affidavits it must be said that in a patent it is to be presumed that a process, if used by one skilled in the art, will produce the product alleged by the patentee and such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. Skilled workers would as a matter of course, in our opinion, if they do not immediately obtain desired results, make certain experiments and adaptations and we agree with the argument of the solicitor that it is not a difficult matter to carry out a process in such fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight, citing *Bullard Company et al. v. Coe*, 147 F.2d 568, 64 USPQ 359 . Possibly more extensive experiments than were made by the affiants herein might have produced a different result." Likewise is *Freeman v. Minnesota Mining and Manufacturing Co.* 9 USPQ2d 1111, "Freeman has the burden of proving that there was no operable technique for making polyethylene supports or that polyethylene itself was an inoperable material. ...Freeman did not offer any proof that one of ordinary skill in the art could not injection-mold the structure of Figure 15 in 1975." A single failure or two cannot meet such a burden of "there was no operable technique". See also *Ex parte Gray* 10 USPQ2d 1922, 1928 which states, "we are of the opinion that, to raise the question of nonenablement, appellants must, at the very

least, provide a declaration by a person having ordinary skill in the subject art that no method was known to him prior to the claimed invention whereby the claimed material might have been synthesized." See also *In re Sasse*, 207 USPQ 107, and also *In re Collins*

174 USPQ 333, which states, "we do agree with the solicitor that Sweedyk's affidavit fails to establish that there was no known or obvious way to make heat exchangers falling within the scope of appellant's claims."

With regard to Himmelsbach II:

3. The two prior art compounds selected both have the 7-propargyl feature. However, none of the comparison species have this 7-propargyl feature (or indeed, any alkyne at all), and hence there is not a proper comparison. These are 5 carbon moieties; the prior art compounds have three carbons. If the 7-propargyl is quashing most or all fo the enzyme activity, then one would expect no actual different to appear between the secondary and tertiary amines. The fact that there is such a difference in the 3-methyl-2-butenyls does not mean that there will be a difference in the propargyls.

In addition, the prior art compounds have the dialkylamino feature, whereas the comparison compounds have just the amino. Thus, the poor result from the prior art compounds could arise from the use of dialkylamino rather than amino. Indeed, that very possibility is explicitly raised and supported in paragraph 9. However, claims 1-2 also have such a feature, permitting dialkylamino. See page 14, definition of R19; 11th from last line of page 25. Applicants cannot argue unexpected effects based on a feature which is in the prior art but is also in the claims as well.

4. Leake also has 7-aralkyl choices; see examples 24-28 and 30. No testing has been done with such compounds as well. 7-benzyl is permitted by the claims and indeed, is seen in some species as well.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The following is a quotation of the second paragraph of 35 U.S.C. 112:
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"General" is indefinite. A formula cannot be both general and specific. Deletion is suggested.

Claims 1-6, 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The lengthy lists, and lists within lists, make it difficult to determine which terms are members of which lists, especially since applicants use commas to separate everything. Applicants cannot rely on indentation to preserve definitions, since this may be lost. This matter cane be resolved easily by numbering the items on these lengthy lists.

Claim 10 is rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly

point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The term "arthritis" is indefinite. By itself, it is not a standard medical term for a specific disease or groups of related diseases, but a general term denoting inflammation of the joints, and may or may not involve inflammation of other parts of the body such as the nails. It mostly commonly refers to any of osteoarthritis, gouty arthritis, or rheumatoid arthritis. These are three totally different and unrelated disorders, which all have "arthritis" in their name and involve inflammation of the joints. Rheumatoid arthritis is an inflammatory disorder causing destruction of articular cartilage. It is an autoimmune condition where the body's immune system attacks its joints. In gouty arthritis, joint inflammation is caused by the formation of monosodium urate monohydrate (MSU) crystals within the joint space. Osteoarthritis is a degenerative cartilage disorder; cartilage breakdown causes bones to rub against each other. Causes include injuries, diseases such as Paget's disease, and long term obesity, but often the cause is unknown. Complicating matters further is that fibromyalgia is sometimes also intended to be included in the loose term "arthritis". There is also Psoriatic Arthritis (including DIP, and spondylitis) which is believed to be autoimmune in origin but is a separate disorder from Rheumatoid arthritis. There is also an assortment of infectious arthritis, i.e. arthritis caused by bacteria, rickettsiae, mycoplasmas, viruses (or vaccinations given to prevent viral infections), fungi, or parasites. Included in this category are various types of septic arthritis, mycotic arthritis, and viral arthritis, such as rubella arthritis, Lyme arthritis, Mumps arthritis, arboviral arthritis, syphilitic arthritis, parvovirus arthritis, tuberculous arthritis, Varicella arthritis, gonococcal arthritis, rubella arthritis, Reiter's syndrome (which includes a form

of arthritis commonly arising from infection by Chlamydia trachomatis) etc. These assorted disorders can arise from quite varied sources. Moreover, in addition to the above, CPDD (sometimes called pseudoosteoarthritis, or pseudogout) arises from Calcium Pyrophosphate Deposition. Systemic onset juvenile idiopathic arthritis (SOJIA), unlike rheumatoid arthritis, appears dependent on IL-1 and dendritic cell malfunction. Menopausal arthritis is due to ovarian hormonal deficiency. Neuropathic arthritis (which comes in several forms, such as Charcot's disease) can arise from sources as diverse as Diabetes Mellitus, Steroid treatment, Leprosy, Chronic alcoholism, Heavy metal poisoning and Neoplastic peripheral neuropathy. There is also type II collagen-induced arthritis (CIA). There is simply no way of knowing which one of these disorders applicants intend. For whichever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended, and applicants must correct the term (paragraph 2).

In addition, such a term cannot be deemed enabled. No one medicine could possibly treat all such diseases generally. They are simply too diverse. Thus, for example, Psoriatic Arthritis, CPDD, syphilitic arthritis and Osteoarthritis have utterly different etiology, and it would be contrary to medical science for one drug to be able to treat all four (paragraph 1).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 7 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 13 of copending Application No. 10467961. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The exact same list of 38 species is being claimed in both cases.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 8-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 14-16 of copending Application No. 10467961. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the two cases are virtually identical. The scope of 10693069 is very slightly narrower, and the provisos are structured slightly differently, but the claims are nearly identical. It is noted that both cases arise from the same 4 German priority documents and that inventorship is the same; a need for two applications is not actually seen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mark L. Berch
Primary Examiner
Art Unit 1624

March 29, 2005